Amendment #3
Solicitation Number
NIAID-DMID-NIHAI2014004

AMENDMENT THREE (3)

OFFICE OF ACQUISITONS
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Purpose of Solicitation amendment:	The purpose of Amendment #3 is to respond to questions received regarding this solicitation.

The hour and date specified for receipt of Offerors remains unchanged – 3:30 PM Eastern Prevailing Time on August 1, 2014.

Offerors must acknowledge receipt of this amendment (as well as all other amendments) on each copy of the proposal submitted. Failure to receive your acknowledgement of all amendments may result in rejection of your proposal.

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

The Government's responses to questions received regarding this solicitation are as follows:

1) **SECTION L – Instructions, Conditions, and Notices to Offerors**

Question: Section L.1.e. LEVEL OF EFFORT (pages 40-41 of the RFP) includes a table listing 3 Labor Categories (Principal Investigator; Professional; and, Technicians/Support). Because this is a level of effort RFP, can the Government provide clarification on what types of professionals or categories of work should be listed as "Professional" versus "Technicians/Support"? Can the Government clarify which tasks within the SOW it anticipates will be included in the "Professional" category to provide guidance on which grouping of employees should be assigned to the category so as to meet the requirement of 5,739 hours during the normal base and option periods?

Response: The tables in Section L.1.e. LEVEL OF EFFORT are intended as an estimated guide for direct labor hour distribution amongst labor categories. The Offeror should use its professional judgment in proposing its labor mix. Offerors may propose a different distribution of labor hours amongst labor categories so long as the total labor hours proposed equal the total amount of labor hours required by the RFP for each contract period and Option Quantity.

With that in mind, in the context of this RFP, the term "Professional" is intended to refer to someone with some amount of subject matter expertise. The term "Technician/Support" is intended to refer to someone who would be carrying out work on behalf of the "Professional." For example, a "Professional" would write an investigational brochure, while a "Technician/Support" staff would edit said document, prepare it for submission, and do the actual submission.

Question: Section L.1.e. LEVEL OF EFFORT (pages 40-41 of the RFP) includes a table of Labor Hours for Option Quantities. This table lists "Professional/Technicians/Support" as the only Labor Category for the Option Quantities. Should Offerors assume that the Principal Investigator position will not need to provide additional support if any Option Quantities are exercised?

Response: Assume that the Principal Investigator will be needed if the option is exercised. Offerors should use their professional judgment in proposing the distribution of labor hours amongst labor categories so long as the total labor hours proposed equal the total hours required by the RFP for the Option Quantities.

Question: Regarding Section L.2.b.1.b. Personnel – Is there any reason the Government would not accept a proposal in which the Principal Investigator position is filled by a consultant to the Contractor?

Response: The Government would not automatically reject a proposal in which the Principal Investigator position is filled by a consultant. However, this situation may present some challenges. Please note that Article I.3. Additional Contract Clauses in the RFP includes FAR Clause 52.219-14, Limitations on Subcontracting. This clause states that "by submission of an offer and execution of a contract, the Offeror/Contractor agrees that in performance of the contract . . . at least 50 percent of the cost of contract performance incurred for personnel shall be expended for employees of the [small business Offeror/Contractor]." In addition, whenever use of a consultant is proposed in any capacity, the Government must consider whether the service can be performed more economically by employment rather than by contracting before authorizing use of the consultant. Also, note Technical Evaluation Factor 2 listed on Page 70 of the RFP, which states that Principal Investigators will be reviewed not only for technical expertise, but also for "managerial leadership that is necessary to carry out, direct and coordinate the specific activities set forth in the Statement of Work, including management of subcontractors/consultants." Also, consider the ramifications on Evaluation Factor 4: Project Management. For example, an issue may arise regarding the fact that the Government only has privity of contract with the successful Contractor – it does not have privity with any subcontractors or consultants.

Question: Regarding Section L.2.c.3-4 (Cost or Pricing Data), does the Government anticipate receiving two or more independent, reasonable offers from responsible small businesses, such that the requirement for Certified Cost or Pricing data will be removed per FAR 15-403-1(c)?

Response: As the Government does anticipate receiving two or more independent, reasonable offers from responsible small businesses, Certified Cost or Pricing Data is not required for initial proposal submissions under this RFP; however, the Government reserves the right to request certification at any point up to award, if necessary.

Question: Regarding Section L.2.c.3-4 (Cost or Pricing Data), the RFP requires the submission of cost and pricing information formatted like Table 15-2 of FAR 15.408. Please confirm that the use of the NIH-provided spreadsheet for detailing estimated costs will meet the requirements of Table 15-2.

Response: As Certified Cost or Pricing Data is not required for initial proposal submissions, cost and pricing information need not follow the formatting of Table 15-2 of FAR 15.408. Proposals must include "Attachment 11: Breakdown of Proposed Estimated Costs (plus fee) with Excel Spreadsheet," as set forth in Attachment 1 – Packaging and Delivery of Proposals. Proposals must also provide cost and pricing information sufficient to satisfy L.2.c.3. Data Other than Certified Cost or Pricing Data (page 61 of the RFP).

Question: Section L.2.c.5. (pages 63-64 of the RFP) sets forth the NIH Salary rate limitation imposed by HHSAR Clause 352.231-70. Please verify that the salary rate limitation for the above-referenced solicitation is $181,500 per year (amount effective February 1, 2014).

Response: The Government verifies that proposals should reflect that no NIH funds may be used to pay a direct annual salary at a rate in excess of the Executive Schedule, Level II, which is currently set at $181,500 per year.

Question: Section L.2.c.5. (pages 63-64 of the RFP) sets forth the NIH Salary rate limitation imposed by HHSAR Clause 352.231-70. It indicates that "an individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract" (emphasis added). If a prime contractor or subcontractor employee has a normal gross annual salary of $200,000 (which would exceed Executive Level II if the employee worked full-time for a year under the contract in question) and only works 100 hours on the contract during a given year, their compensation for the direct effort under the contract will equal approximately $9,615 ($200,000/2080 = $96.15 * 100 = $9,615). Please confirm that in this situation there would be no violation of 352.231-70, because the compensation paid for the direct effort under the contract is far below the Executive Level II threshold.

Response: To clarify, as set forth in P.L. 112-74, no NIH funds may be used to pay the direct annual salary of an individual at a rate in excess of the Executive Schedule, Level II. Therefore, any hourly amount billed for an employee on a particular invoice must be calculated from a yearly base salary at or below the Executive Schedule, Level II salary rate (currently set at $181,500 per year).

2) ATTACHMENT 1 – Packaging and Delivery of Proposals

Question: Attachment 1 requires that bidders submit their proposals via disc (CD/DVD) and via the eCPS system. Because subcontractors prefer to provide sensitive or proprietary cost data directly to the Government, what is the process for subcontractor "sealed" submissions for the business volume, i.e., confidential pricing information?

Response: For this solicitation, proposed subcontractors will be permitted to send confidential pricing information under separate cover directly to the Government via disc, without submitting this information online via the electronic Contract Proposal Submission system (eCPS). All other packaging and delivery instructions set forth in Attachment 1 still apply, and all proposal information must be received by the hour and date specified for receipt of proposals for the proposal to be timely.

Question: Amendment # 2 (page 2) cites two "exceptions" to the page limitation: (1) Electronic and Information Technology Accessibility, Section 508 Compliance; and (2) Standard Operating Procedures (SOPs). Then, the next sentence in that Response paragraph only notes Section 508 Compliance (but omits the SOPs), as an item that can be in an attachment outside of the page limit. Please confirm that SOPs are in fact excluded from the page limit, and that SOPs can be in a "separately numbered attachment" as well. Does the Government's use of the term "attachments" also encompass "appendices" – to which the exceptions and page limits also apply? Please confirm.

Response: Regardless of how the information is assembled, every page of the Technical Proposal will be included in the page limitation other than the Standard Operating Procedures, Section 508 Compliance documentation, and any of the following (as specified in Page 3 of Attachment 1): Title Page, Back Page, Table of Contents, and Section Dividers that do not contain information other than the title of the Section.

For ease of verifying conformance with the page limitation, the SOPs and Section 508 Compliance documentation should be separately numbered.

Question: Would a cross-reference matrix which merely maps the elements in the technical proposal with the requirements in the RFP for the ease of the reviewers be included in the technical proposal page limit?

Response: A cross-reference matrix will be included in the Technical Proposal page limit. The Offeror should use its professional judgment to consider the value of including a matrix in preparing its proposal for the technical review committee.

Question: Are resumes included in the page limit, or can they be in an attachment / appendix that does not count toward a page limitation?

Response: Resumes / CVs will be included in the Technical Proposal page limit. Also, please note that Page 5 of Attachment 5 – Additional Technical Proposal Instructions states "Limit the CVs to 2-3 pages . . . ."

3) ATTACHMENT 3 – Statement of Work

Question: Attachment 3 in Section 1.B.3) ii. states to "provide draft briefing packets to the COR within 10 business days of request from COR". We assume the 10 business day window will not begin until the Contractor has received all documents and information required from the COR or from any 3rd Party not under Contractor's control. Please confirm.

Response: Confirmed.

Question: Will CSR submissions be both paper and electronic? If yes, can you provide an approximate percentage for each type of submission?

Response: For purposes of preparing your proposal, assume that CSR submission will initially be 95% paper and 5% electronic. However, it is estimated that during the period of performance, including option years, all submissions will eventually become electronic.

Question: In Attachment 3 on page 1 of 5 (Statement of Work) it states that "Currently, DMID sponsors approximately 100 INDs or MFs which span more than 200 Clinical Trials."…. For costing purposes, how many of the existing INDs (which will potentially be imported into the awardee's system) are maintained electronically versus as hard copy only?

Response: While the number may vary up to the time of contract award, currently there are 3 existing INDs that are being maintained electronically.

Question: Please provide clarification on the retention, archiving, and destruction policies for document management. Would the contractor be responsible for the destruction of documents?

Response: Please refer to the Code of Federal Regulations regarding recordkeeping and record retention requirements. The Contractor would be responsible for the destruction of documents; however, please note that nothing is to be destroyed without explicit approval from DMID.

Question: Will the Contractor be expected to use any DMID owned or provided systems related to regulatory submission information management? If so, which ones? What are the existing IT systems for tracking and managing the workflow?

Response: The successful Offeror will not be using any DMID owned or provided IT systems. Offerors should use their professional judgment in determining what type of IT systems to include in their proposals.

Question: Can the Government confirm to what extent the Offeror will be responsible for migration from legacy systems? What is the current file structure?

Response: Existing data will be provided to the awardee in Microsoft Excel, Microsoft Access, or similar format. The awardee will be fully responsible for entering the data into a system that will allow them to fulfil all the requirements within the SOW.

Question: What countries does DMID currently manage clinical trials in which will be subject to regulatory support under this contract?

Response: Assume that regulatory support may be needed in any ex-U.S. country. As stated in Amendment 2, describe the process by which your organization will approach this issue for any ex-U.S. country, as needed. Also, provide specific examples that demonstrate your organization's experience in providing this service, using your professional judgment to select representative ex-countries.

Question: Is GMP inventory included in the scope of the audits for this contract?

Response: Yes.

Question: Can the Government confirm whether the costs associated with the Transition In and Transition Out activities are included in the hours identified for the Base and Option Years?

Response: Confirmed.

4) ATTACHMENT 6 – Additional Business Proposal Instructions and Uniform Cost Assumptions

Question: In Attachment 6; Section 3 Uniform Cost Assumptions, Technical Cost Assumptions A.1. it states that the offeror should assume 8,500 3-inch binders for hard copy document storage. Should the cost of ACCO binders and tabs for hard copy IND submissions to the FDA also be included in the budget? If so, how many binder volumes should we assume for costing purposes?

Response: The Offeror should use its professional judgment to estimate all costs associated with IND submissions, taking into consideration the Uniform Cost Assumptions provided in Section 3.1.B. in Attachment 6, as well as Responses in this Amendment regarding electronic vs. paper submissions.

Question: Attachment 6, Section 3, Technical Cost Assumptions states that there will be 100 active and 175 inactive INDs, IDEs, and/or MFs requiring storage in a Regulatory Management Information System and in hard copy at Offeror's location. For cost estimating purposes, what is the average number of pages for the active and inactive INDs, IDEs, and MFs that will be transitioned at contract award?

Response: For purposes of preparing your proposal, assume an average of 1,000 pages for each active and inactive IND, IDE, and MF.

Question: Attachment 6, page 2, Item 3.1.B.5 (FDA Meetings and Teleconferences) specifies contractor participation in 3 meetings and 7 teleconferences with the FDA per year. However, Attachment 6, page 3, Item 3.2.F (Meetings with the FDA) tells offerors to assume travel for 3 contractor staff to participate in 10 formal meetings per year with the FDA within a 50-mile radius of Washington, D.C. Should offerors assume 10 in-person meetings in Washington, D.C. with the FDA or 3 in-person meetings and 7 teleconferences?

Response: For purposes of preparing your proposal, assume 3 in-person meetings and 7 teleconferences with the FDA per year for new regulatory support activities.

Question: Should offerors also include the 2 ongoing FDA meetings (Attachment 6, page 1, Item 3.1.A.10) in their face-to-face meeting or teleconference total?

Response: For purposes of preparing your proposal, assume 2 teleconferences with the FDA for ongoing activities during the first year of performance.

Question: Regarding RFP Attachment 6, Section 3.1: "Technical Cost Assumptions" Item A.9 (pg. 1 of 3), Ongoing Activities – Four audits/site visits: Amendment # 2 clarified the location of these audits/visits, but please provide additional clarification on the following:

- Should offerors propose these "ongoing activities" audits/site visits in Year 1 only (i.e., subsequent years will only have "new regulatory support activities" audits/visits @ 8 per year)? Or will these "ongoing" audits/visits continue at 4/year throughout the full 7 years?
- What duration (# days) should offerors assume for these audits/visits (e.g., two-day visits, as per the "new regulatory support activities" audits/visits?)

Response: For purposes of preparing your proposal, assume that the above-referenced audits for ongoing activities will only be necessary during the first year of performance and will require two days per audit.